CLAIM AMENDMENTS

Claims 1-25 (cancelled).

26 (previously amended): A storage-stable, self-emulsifying, and non-aqueous, preconcentrate of a taxane in a microemulsion comprising a taxane dissolved in a carrier system, which carrier system consists essentially of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants;

up to 35% w/w diethylene glycol monoethylether; and

up to 40% w/w of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, and combinations thereof;

wherein the preconcentrate, when mixed with water or simulated gastric fluid, forms a liquid having an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

27 (previously amended): The self-emulsifying preconcentrate of claim 26, wherein the carrier system consists of 15 to 75% w/w of the hydrophobic component.

28 (previously amended): The self-emulsifying preconcentrate of claim 26, wherein the carrier system consists of up to 30% w/w of the hydrophilic component.

29 (previously amended): A storage-stable, self-emulsifying, and non-aqueous preconcentrate of at least one taxane in a composition consisting essentially of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, 1,2-propylene glycol, ethanol, and combinations thereof;

wherein the preconcentrate, when mixed with water or simulated gastric fluid, gives an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

30 (previously amended): The preconcentrate of claim 29, wherein the hydrophilic component is selected from the group consisting of 1,2-propylene glycol and ethanol.

31 (previously added): An orally administrable pharmaceutical composition consisting essentially of the preconcentrate of claim 29 in a pharmaceutically acceptable carrier or diluent.

32 (previously added): A parenterally injectable pharmaceutical composition consisting essentially of the preconcentrate of claim 29 in a pharmaceutically acceptable diluent.

33 (previously added): The preconcentrate of claim 29 filled in a soft or hard gelatin capsule.

34 (previously amended): The preconcentrate of claim 29, wherein the preconcentrate also includes an inhibitor of P-glycoprotein transport system or an inhibitor of cytochrome P450 enzyme.

35 (previously amended): The preconcentrate of claim 29, wherein the preconcentrate comprises grapefruit extract or a component thereof.

36 (previously amended): The preconcentrate of claim 29, wherein the taxane is paclitaxel or docetaxel.

37 (previously amended): A method of orally or parenterally administering a taxane to a subject in need of same comprising administering a dose of a storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane consisting essentially of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% w/w of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, and combinations thereof;

wherein the preconcentrate, when mixed with water or simulated gastric fluid, gives an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

38 (previously amended): The method of claim 37, wherein the taxane is solubilized in the preconcentrate.

39 (previously added): A storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane in a microemulsion comprising a taxane dissolved in a carrier system, which carrier system consists essentially of:

10 to 80% w/w of a hydrophobic component;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% w/w of a hydrophilic component.

40 (previously added): The preconcentrate of claim 39, wherein the preconcentrate forms a liquid having an average droplet size of at most 10 microns when mixed with water or simulated gastric fluid.

41 (previously added): The preconcentrate of claim 40, wherein a dose of the preconcentrate has a taxane bioavailability of 25 to 60% upon oral administration.

42 (previously added): The preconcentrate of claim 41, wherein at least a portion of the hydrophilic component consists of ethanol, such that the carrier system contains at least 6% w/w ethanol.

43 (previously added): The preconcentrate of claim 39, wherein the preconcentrate, when mixed with an aqueous medium and heated to 20-37° C, forms a liquid having an average droplet size of at most 10 microns.

44 (previously added): The preconcentrate of claim 43, wherein the preconcentrate, upon oral administration, forms a microemulsion *in situ* in the gastrointestinal tract.

45 (previously amended): A storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane in a microemulsion comprising a taxane dissolved in a carrier system, which carrier system consists essentially of:

10 to 80% w/w of a hydrophobic component;

20 to 80% w/w of a surfactant component; and

6% to 40% w/w of a hydrophilic component, at least a portion of which hydrophilic component consists of ethanol, such that the carrier system contains at least 6% w/w ethanol.

46 (previously added): The preconcentrate of claim 45, wherein the surfactant component consists of one or more surfactants selected from the group consisting of polyoxyethylene-sorbitan-fatty acid esters, polyoxyethylene fatty acid esters, α-tocopherol, α-tocopheryl polyethylene glycol succinate, α-tocopherol palmitate, α-tocopherol acetate, PEG glyceryl fatty acid esters, propylene glycol mono- or di-fatty acid esters, sorbitan fatty acid esters, polyoxyethylene-polyoxypropylene co-polymers, glycerol triacetate, monoglycerides, and acetylated monoglycerides.

47 (previously added): The preconcentrate of claim 46, wherein the preconcentrate forms a liquid having an average droplet size of at most 10 microns when mixed with water or simulated gastric fluid.

48 (previously added): The preconcentrate of claim 47, wherein a dose of the preconcentrate has a taxane bioavailability of 25 to 60% upon oral administration.

49 (previously added): The preconcentrate of claim 45, wherein the preconcentrate, when mixed with an aqueous medium and heated to 20-37° C, forms a clear liquid having an average droplet size of at most 10 microns.

50 (previously added): The preconcentrate of claim 49, wherein the preconcentrate, upon oral administration, forms a microemulsion *in situ* in the gastrointestinal tract.

51 (previously amended): A storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane in a microemulsion comprising a taxane dissolved in a carrier system, which carrier system consists essentially of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more surfactants selected from the group consisting of a polyoxyethylene-sorbitan-fatty acid ester, a polyoxyethylene fatty acid ester, a polyoxyethylene castor oil derivative, α-tocopherol, α-tocopheryl polyethylene glycol succinate, α-tocopherol palmitate, α-tocopherol acetate, a PEG glyceryl fatty acid ester, a propylene glycol mono- or di-fatty acid ester, a sorbitan fatty acid ester, a polyoxyethylene-polyoxypropylene co-polymer, glycerol triacetate, a monoglyceride, an acetylated monoglyceride, and combinations of any thereof; and

6% to 40% of a hydrophilic component, at least a portion of the hydrophilic component consisting of ethanol, such that the carrier system contains at least 6% w/w ethanol.

52 (previously added): The preconcentrate of claim 51, wherein a dose of the preconcentrate has a taxane bioavailability of 25 to 60% upon oral administration.

53 (previously amended): An injectable pharmaceutically acceptable composition consisting essentially of a storage-stable, self-emulsifying, and non-aqueous preconcentrate of at least one taxane in a composition consisting essentially of:

10 to 80% w/w of a hydrophobic component;

20 to 80% w/w of a surfactant component; and

6% to 40% w/w of a hydrophilic component,

wherein (a) at least a portion of which hydrophilic component consists of ethanol, such that the composition contains at least 6% w/w ethanol, (b) the surfactant component of the composition consists of one or more non-ionic surfactants, or (c) conditions (a) and (b) apply.

54 (previously added): A storage-stable, self-emulsifying, and non-aqueous, preconcentrate of a taxane in a microemulsion consisting of a taxane dissolved in a carrier system, which carrier system consists of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants;

up to 35% w/w diethylene glycol monoethylether; and

up to 40% w/w of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, and combinations thereof;

wherein the preconcentrate, when mixed with water or simulated gastric fluid, forms a liquid having an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

55 (previously added): A storage-stable, self-emulsifying, and non-aqueous preconcentrate of at least one taxane in a composition consisting of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, 1,2-propylene glycol, ethanol, and combinations thereof;
wherein the preconcentrate, when mixed with water or simulated gastric fluid, gives an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

56 (previously added): A method of orally or parenterally administering a taxane to a subject in need of same consisting of administering a dose of a storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane consisting of:

10 to 80% w/w of a hydrophobic component selected from the group consisting of a triglyceride, a diglyceride, a monoglyceride, a free fatty acid, a fatty acid ester, a fish oil, a vegetable oil, and combinations thereof;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% w/w of a hydrophilic component selected from the group consisting of a hydroxyalkane, a dihydroxyalkane, a polyethylene glycol having an average molecular weight of at most 1000, and combinations thereof;

wherein the preconcentrate, when mixed with water or simulated gastric fluid, gives an average droplet size of at most 10 microns, and a dose of the preconcentrate has a taxane bioavailability of 25 to 60% of the taxane in the dose upon oral administration.

57 (previously added): A storage-stable, self-emulsifying, and non-aqueous preconcentrate of a taxane in a microemulsion consisting of a taxane dissolved in a carrier system, which carrier system consists of:

10 to 80% w/w of a hydrophobic component;

20 to 80% w/w of a surfactant component consisting of one or more non-ionic surfactants; and

up to 40% w/w of a hydrophilic component.

58 (new): The preconcentrate of claim 29, wherein the taxane is paclitaxel and is present in an amount of from 1.36% to 5.7% by weight of the preconcentrate.

59 (new): The preconcentrate of claim 29, wherein the composition consists of 15 to 75% w/w of the hydrophobic component.

60 (new): The preconcentrate of claim 29, wherein the hydrophobic component consists of a medium chain triglyceride.

61 (new): The preconcentrate of claim 29, wherein the hydrophobic component consists of propylene glycol dicaprylate/caprate and is present in an amount of from 31.2 to 34.9% by weight of the preconcentrate.

62 (new): The preconcentrate of claim 29, wherein the surfactant component consists of polyoxyl 40 hydrogenated castor oil, PEG-8 glyceryl caprylate/caprate, and glycerol monocaprylate.

63 (new): The preconcentrate of claim 62, wherein the polyoxyl 40 hydrogenated castor oil is present in an amount of from 32.2 to 38.8% by weight of the preconcentrate.

64 (new): The preconcentrate of claim 62, wherein the PEG-8 glyceryl caprylate/caprate is present in an amount of from 8.1 to 9.7% by weight of the preconcentrate.

65 (new): The preconcentrate of claim 62, wherein the glycerol monocaprylate is present in an amount of from 11.3 to 13.6% by weight of the preconcentrate.

66 (new): The preconcentrate of claim 29, wherein the hydrophobic component consists of caprylic/capric triglyceride.

67 (new): The preconcentrate of claim 66, wherein the caprylic/capric triglyceride is present in an amount of 28.7% by weight of the preconcentrate.

68 (new): The preconcentrate of claim 26, wherein the taxane is docetaxel.

69 (new): The method of claim 37, wherein the taxane is docetaxel.

70 (new): The preconcentrate of claim 39, wherein the taxane is docetaxel.

71 (new): The preconcentrate of claim 45, wherein the taxane is docetaxel.

72 (new): The preconcentrate of claim 51, wherein the taxane is docetaxel.

73 (new): The composition of claim 53, wherein the taxane is docetaxel.

74 (new): The preconcentrate of claim 54, wherein the taxane is docetaxel.

75 (new): The preconcentrate of claim 55, wherein the taxane is docetaxel.

76 (new): The method of claim 56, wherein the taxane is docetaxel.

77 (new): The preconcentrate of claim 57, wherein the taxane is docetaxel.